Engage Psychotherapy to Promote Connectedness in Caregivers

NCT04176601

Statistical Analysis Plan

6/30/2019

P30AG064103-Pilot2

Statistical Design & Power: Study 2

We will enroll n=30 participants, anticipating n=24 will begin the intervention (considering exclusion criteria, interest in the intervention) and a conservative potential attrition rate of 20% (15% is more likely based on the PIs' prior studies). Based on our prior RCT of Engage—including its flexible structure (e.g., accommodating phone sessions when needed) and high acceptability—we expect most participants will complete a full course of Social Engage (i.e., at least 6 sessions out of 8 allowed; we had 88% achieve this in our prior Engage study). We have also successfully retained caregivers in our intervention research. For Dr. Heffner's clinical trials, one of which includes an 8-week home-based computer intervention, and the other a 9-session in-person mindfulness group training (i.e., requiring attendance at a local community site), attrition rate continues to be very low, ~10%. Given these considerations, we anticipate n=20 participants will provide follow-up data and complete a full course of Social Engage. This calculation includes our expected recruitment rate (n=4 per month), projections about the length of time between enrollment and commencement of therapy (1-2 weeks), amount of time to complete the intervention (maximum of 3 months, including two weeks buffer for missed sessions), and time to complete follow-up assessments. Given start-up and time for data analysis, our study resources and recruitment infrastructure will support running our participants through all study procedures within the 1-year timeline.

This is a Stage One (NIH Stage Model) intervention development study. Aim 1 examines feasibility of Social Engage psychotherapy for caregivers; Aim 2 explores which behavioral strategies are most useful for caregivers when completing Social Engage psychotherapy; Aim 3 is to examine potential efficacy of Engage by examining satisfaction with the intervention and changes in social connectedness over the course of therapy. For Aim 3, we will measure a behavioral indicator of connectedness (quality and quantity of positive social interactions), a psychological indicator of connectedness (loneliness), and indicators of well-being at baseline, 1 month, end of treatment (3 months), and 3 months after completing treatment (6 month follow-up) to estimate the length of treatment needed for improvement; to estimate the proportion of participants who respond to treatment; and to examine the durability of the effect (to inform a fully powered, randomized efficacy trial).

Participants will be characterized at baseline with regards to demographic characteristics, degree of social disconnectedness, caregiver distress, well-being (depressive symptoms, quality of life), cognitive function, and relationship satisfaction with the person they care for. For Aim 1 the number of subjects and the number of sessions completed by each will be examined to determine if at least 80% of subjects will be willing to start Social Engage and at least 75% complete a full dose of the intervention. Aim 2 is to determine the most useful barrier strategies to use with caregivers. We will tabulate how often each strategy is used within and across participants. Qualitative analyses will be conducted with interview data from participants at follow-up regarding their perceptions of effective barrier strategies (Aim 2) and effective/ineffective aspects of the therapy in general (Aim 3). Aim 3 is to obtain evidence for a signal for efficacy with regards to social connectedness. Baseline data from the STAR core battery will be used: a behavioral indicator of social connectedness (quality and quantity of positive social interactions), a psychological indicator of connectedness (loneliness), mechanisms of change (autonomy, competence, and relatedness), and indicators of well-being (psychological distress and quality of life). Assessments will be repeated after 1 month, the end of intervention (3 months), and at 6-month follow-up. Follow-up data at one month will be used to estimate the length of treatment needed to demonstrate improvement; follow-up data at the end of treatment will be used to estimate the proportion of participants who demonstrate increases in social connectedness by the end of the intervention; and follow-up data at 6-months will be used to demonstrate the proportion of participants who maintain gains in connectedness after completing the intervention (and interacting with the study therapist).